

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

March 17, 2020

Casey Pehrson Regulatory Consultant Micro-Science, LLC 755 Tri-State Parkway Gurnee, IL 60031

Subject: Label Amendment – Adding the Emerging Viral Pathogens Claims

Product Name: Opti-cide 3

EPA Registration Number: 70144-1 Application Date: 02/07/2020 Decision Number: 560566

## Dear Ms. Pehrson:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-

09/documents/emerging\_viral\_pathogen\_program\_guidance\_final\_8\_19\_16\_001\_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

- 2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
- 3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
  - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
    - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
      - A. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
      - B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
      - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
    - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page

(www.oie.int/wahis 2/public/wahid.php/Diseaseinformation/WI).

- A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is small non-enveloped, large non-enveloped, enveloped.
- B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
- 4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

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> 5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Roatvirus WA, Rhinovirus and Murine Norovirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at Heffernan. Aline@epa.gov.

Sincerely,

John Hebert, Chief Regulatory Management Branch 1

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Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure

## Opti-Cide® 3

{Alternate Brand Names:} [Opti-Cide®],[Opti-Cide® 1],[Opti-Cide® 2]

{Insert marketing statements, as appropriate, from Marketing Copy and/or Directions for Use}

A ativa	Ina	radia	nto.
Active	: ma	reale	ents.

n-Alkyl (60% C <sub>14</sub> , 30% C <sub>16</sub> , 5% C <sub>12</sub> , 5% C <sub>18</sub> ) dimethyl benzyl ammonium chloride	0.154%
n-Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> ) dimethyl ethylbenzyl ammonium chloride	0.154%
Isopropanol	
Other Ingredients	78.692%
Total	100.000%

## Keep Out of Reach of Children CAUTION

[See ([back] [side]) panel for First Aid and additional Precautionary Statements.]

EPA Reg. No. 70144-1 **EPA Est.** 

Net Contents: \_\_\_ \_US ([gal] [fl. oz.]) [(\_ {2 fluid ounces through 275 gallons}



{Flag image is optional} [Made in the U.S.A.]

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- ([]) Denotes one of the options within the brackets must be chosen
- { } Denotes language that does not appear on the market label
- () Denotes language that is intended to be included on label with parenthesis included
- The phrase "This product" may be replaced with the appropriate product name

{Marketing Copy}

## {General Marketing Claims}

Antibacterial

Antimicrobial

Cleaner

Cleans

Germicidal

Effective

For use ([on] [in]) {insert Use Sites or Surfaces}

Fragrance free

For use on instrument(s) and non-critical medical devices

Healthcare

**Hospital Uses** 

Housekeeping [and in-home use]

[Pre-Cleaning] Instrument [and non-critical medical device] soak

[Hospital] [Medical] [Surgical] [Dental] [Veterinary] [Animal Care] [Home Health Care] [Long Term Care] [EMS] {or other use-sites as described}

## ACCEPTED

03/17/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

70144-1

Multi-purpose

For use on hard, non-porous surfaces when used as directed

For use on hard, non-porous non-food contact surfaces [when used as directed]

For use on hard, non-porous food contact surfaces [when used as directed]

For use on soft surfaces when used as directed

Floor Cleaner

Ultrasonic Cleaner Concentrate

Clean

Cleans on contact

Use to clean away particular matter including soil, and other organic debris

Pre-clean(s) scope surfaces prior to terminal reprocessing

Barber ([disinfectant][sanitizer][cleaner])

Salon ([disinfectant][sanitizer][cleaner])

Foot Spa ([disinfectant][sanitizer][cleaner])

Deodorizer [Deodorizes] [Deodorize]

([Help(s)] [eliminate(s)]) ([smells] [odors])

Improved Uses

No mixing

No confusion

Ready[-]to[-]Use

RTU

Suitable for use on non-food contact surfaces when used as directed

Suitable for use on hard, non-porous food contact surfaces when used as directed

Suitable for use on soft, non-food contact surfaces when used as directed

Spot Cleaner

Spot Cleaning of {insert Surfaces}

This product is effective ([in] [at]): {insert Use Site or Surface}:

Contains no perfumes

Refillable ([container] [bottle])

Aids in the reduction of cross-contamination on treated surfaces.

([With] [Contains]) Rust Inhibitor

Contains no [artificial] coloring dyes

Will not stain [vinyl] [surfaces]

#### {Disinfectant Marketing Claims}

Disinfectant

Disinfectant [/] Cleaner {or} Cleaner [/] Disinfectant

Disinfectant and Cleaner [for] {Insert Appropriate Use Sites or Surfaces}

**Disinfecting Cleaner** 

Disinfects hard, non-porous surfaces in ([2] [3]) (as appropriate) minutes when used as directed (use with appropriate contact time kill claims)

[Disinfectant] [Disinfecting] instrument soak with rust inhibitors

Bactericidal

**Broad Spectrum Disinfectant** 

Fungicidal

Kills ([Bacteria], [Viruses\*], [Fungi], [Tuberculosis [(TB)]]) on hard, non-porous inanimate surfaces such as {insert Surfaces}

Kills ([Bacteria,] [Viruses\*], [Fungi,] [Mycobacterium-tuberculosis [(var. bovis)]]) in ([2] [3]) minutes as directed {use with appropriate disinfectant/virucidal claims}

2-Minute [Inanimate] Hard, Non-porous Surface Disinfectant (use with appropriate 2 minute disinfectant claims)

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3-Minute [Inanimate] Hard, Non-porous Surface Disinfectant (use with appropriate 3 minute disinfectant claims)

Kills ([Hydrophilic Viruses\*], [Lipophilic Viruses\*], [Enveloped Viruses\*], [Non-enveloped Viruses\*]

Kills {insert organism from list of approved organisms}

Kills Flu Viruses

Floor Disinfectant

Disinfects

Hard, Non-Porous Surface Disinfectant and Cleaner

Kills MRSA

Kills H1N1 Influenza A Virus (formerly called "swine flu")

([Medical] [/] [Surgical] [/] [Dental] [/] [Hospital]) Surface and Equipment Disinfectant Cleaner

Salon Disinfectant

Same product will ([disinfect], [sanitize], [clean])

Scope ([pre-cleaning] [pre-cleaner])

Tuberculocidal

Virucidal\* [Virucide\*]

Kills [Enveloped] [Non-Enveloped] Viruses\*

One product ([to] [clean[s]], [and] [sanitize[s]], [and] [disinfect[s]])

This product is effective for [cleaning], [sanitizing], [and] [disinfecting]

When used as directed this product effectively [cleans], [sanitizes] [and] [disinfects] hard, non-porous surfaces such as {insert Surfaces that are not soft surfaces}

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A Virus.

This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against Avian Influenza A Virus ATCC VR-2072 and Influenza Virus Strain A2/Hong Kong and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza virus.

This product has demonstrated effectiveness against Influenza A Virus and is expected to inactivate all Influenza A Viruses including Pandemic 2009 H1N1 Influenza virus.

This product has demonstrated effectiveness against Avian Influenza Virus ATCC VR-2072 and Influenza Virus Strain A2/Hong Kong and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 [formerly called "swine flu"].

## {Sanitization Marketing Claims}

Non-food contact sanitizer

Soft surface sanitizer against Staphylococcus aureus and Enterobacter aerogenes

Food contact sanitizer

Kills Bacteria on soft, non-food contact surfaces in 10 Seconds

Kills Bacteria on hard, food contact surfaces in 1 Minute

1-Minute Food Contact Surface Sanitizer

Kills ([99.9% of Bacteria] [Germs])

10-Second Soft Surface Sanitizer

Floor Sanitizer

Sanitizer

Soft, Non-Food Contact Surface Sanitizer

Hard, Non-porous, Non-food Contact Surface Sanitizer

Hard, Non-porous, Food Contact Surface Sanitizer

Spa Clipper Blade ([Sanitizer (Not For Use in California)] [Disinfectant])

Kills 99.9% of Staphylococcus aureus and Enterobacter aerogenes in 10 Seconds on Soft and Hard, Non-Food Contact Surfaces

Kills 99.9% of Staphylococcus aureus and Escherichia coli in 1 Minute

Salon Sanitizer

Sanitizes ([Hard, Non-porous, Non-food Contact Surfaces] [and] [Soft, Non-Food Contact Surfaces]) [in 10 seconds]

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Sanitizes Hard, Non-porous Food Contact Surfaces [in 1 minute]
For use on soft surfaces {for sanitization use only}
For use on hard, non-porous food-contact surfaces {for food contact sanitization use only}
For use on hard, non-porous non-food contact surfaces
Hard, Non-Porous and Soft Non-food Contact Surface Sanitizer

## {Use Sites:}

{Note: If listing Use Sites from this section, the phrase beginning with "This product..." below must be included}

This product can be used ([in] [at]) (the following locations): Acute care facilities, air transport facilities, airports, airplane interiors, amusement parks, ambulatory care centers, ambulatory care facilities, anesthesia areas, animal/pet care facilities, animal control facilities, animal control vehicles, animal breeding facilities, animal detention facilities, animal hospitals, animal laboratories, animal research facilities, animal rescue shelters, animal shelters, animal show facilities, animal trailers, apartments, arboretums, arcades, athletic training facilities, athletic locker rooms, ATM surfaces, automatic teller machine (ATM) facilities [surfaces], auto facilities, autopsy rooms, avian care facilities, avian facilities, avian units, bakeries, banks, barber shops, bathroom facilities, bathrooms, bedrooms, blood banks, banquet hall facilities, bioskill laboratories, blood drawing centers, blood units, blood pheresis facilities, body piercing salons, body service facilities, body storage facilities, botanical gardens, bowling alleys, bus facilities, bus stations, cab facilities, cadaver processing areas, canine facilities, canine units, cardiac catheterization labs, cardiac catheterization laboratories, cash dispensing machines, casinos, Cat-scan ([laboratories] [labs]), central instrument reprocessing facilities, child care facilities, clean rooms, clinical areas, colleges, condominiums, convention facilities, conference centers, conference room fixtures, correctional facilities, CS ([laboratories] [labs]), CT ([laboratories] (labs), currency exchanges, day care centers, day care schools, day spas, delivery units, dental care facilities, dental laboratories, dental offices, detention facilities, dialysis centers, dialysis units, dissection labs, doggy day care centers, drug preparation facilities, drug preparation rooms, early learning centers, electrolysis facilities, emergency medical service (EMS) units, emergency rooms, endoscopy centers, endoscopy facilities, endoscopy departments, entertainment facilities, environmental services facilities, equine facilities, equine units, esthetician facilities, eye care facilities, exam rooms, examination rooms, feline facilities, feline units, fire departments, fire/rescue departments, florists, food processing facilities, foot spas, foreign currency exchange facilities, foreign currency exchanges, forestry services, funeral homes, gaming facilities, garden centers, general public facilities, GI ([laboratories] [labs]), golf courses, grocery stores, grammar schools, grooming facilities, grounds keeping services, gymnasiums, gyms, habitats, hair salons, health clubs, health care facilities, ambulance helicopter interiors, high schools, holding cells, home care patient rooms, home health care facilities, homes, hospice rooms, hospitality facilities, hospitals, hotels, household bathrooms, housekeeping rooms, hydrotherapy facilities, hydrotherapy rooms, infant care facilities, inhome health care rooms, instrument reprocessing areas, intensive care units (ICUs), isolation rooms, jails, kiosks, kindergartens, kitchens, labor units, laboratories, landscaping services, lasik eye centers, lawn services, learning institutions, limousine facilities, living rooms, lockup facilities, lockups, long-term care facilities, lunchrooms, medical facilities, medical offices, medivans, MICUs, middle schools, money handling facilities, morgues, mortuary facilities, mortuaries, motels, movie theaters, MRI facilities, MRI ([laboratories] [labs]), nail salons, neonatal intensive care units (NICUs), newborn nurseries, nuclear medicine facilities, nurseries, nursery schools, nursing homes, occupational therapy centers, occupational therapy facilities, oncology areas, operating rooms, ophthalmology centers, ophthalmology facilities, ophthalmology units, optometric offices, oral health care facilities, orthodontic offices, outpatient care facilities, outpatient facilities, outpatient surgery centers, patient care rooms, pathology rooms, pediatric units, pedicure salons, personal care service facilities, pet homes, pet motels, pet spas, pet stores, pharmacies, physical therapy centers, physical therapy facilities, plasma pheresis centers, plasma pheresis facilities, pheresis units, post-op rooms, post-operative rooms, pre-op areas, pre-operation areas, pre-schools, primary care facilities, prisons, public facilities, public bathrooms, public transportation facilities, radiology rooms, reception areas. recovery rooms, recreation facilities, rehabilitation facilities, rescue departments, respiratory therapy facilities, reptile habitats, restaurants, restroom facilities, retail stores, rodent facilities, rodent units, schools, sleeping rooms, scope reprocessing rooms, shopping malls, sick room facilities, sick rooms, skilled nursing centers, skin care facilities, skin care salons, snack shops, spas, SPD ([laboratories] [labs]), tanning salons, tattoo studios, taxi facilities, taxi cab

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facilities, theaters, toilet facilities, train facilities, train stations, transport vehicles, transportation waiting rooms, tree services, universities, urgent care centers, urgent care facilities, veterinary hospitals, waiting rooms, weight training facilities, X-ray rooms, x-ray equipment surfaces, zoos and other similar establishments.

## {Surfaces:}

(Note: If listing Surfaces from this section, the phrase beginning with "This product..." below must be included)

{Note: Should any of the following surfaces be listed on the market label, the appropriate food contact sanitization directions must be included: mouth bits, breast pump surfaces, toys, non-porous cutting boards, dental impressions, diving snorkels, mouth guards, play toys, water bowls, washing bowls}

{Note: If listing endoscopes or endoscope surfaces, the "For use to [pre-clean] [pre-treat] flexible endoscopes prior to handling during terminal reprocessing" Directions for Use must be used}

This product can be used on the following surfaces: inanimate surfaces such as those made of acrylic, metals (aluminum, brass, copper, stainless steel, chrome), sealed granite, glass, plastics (polycarbonate, polypropylene, polystyrene and polyvinylchloride (PVC)), clear plastics, hard, non-porous rubber, Plexiglas<sup>®</sup>, vinyl as well as coated. laminated and painted surfaces, air evacuation transport units, air transport units, air vents surfaces, airplane fixtures, airplane interiors, ambulance interior surfaces, ambulances, amusement machine surfaces, analgesia equipment surfaces, anesthesia machines, animal cages, animal habitats, apnea monitors, aquariums, armrests, athletic facility fixtures, athletic mats, athletic equipment, athletic protective equipment, ATM touch buttons, attendant seats, tables, backboards, balloon pumps, bank teller surfaces, bar tops, bassinets, bathing tubs, bathroom facilities, bathroom fixtures, bathroom surfaces, bathtubs, bedrails, beds, bedside devices, bedside tables, bedside stands, biohazard team equipment, biological monitoring devices, bird cage surfaces, birthing room fixtures, mouth bits, blood bank equipment surfaces, blood drawing surfaces, blood pressure equipment, blood pressure units, bowls, breathing monitors, breast pump surfaces, brushes, cabinets, cages, call buttons, cadavers, cardiac monitors, carpet(s), cash register surfaces, cash registers, cat litter boxes, carts, central supply equipment, chainsaw blades, chairs, changing tables, chest pumps, classroom fixtures, clipper blade, clippers, cloth furniture surfaces, coated mattresses, coated pillows, coin counter surfaces, coin dispensers, collars, colon equipment surfaces, combs, commodes, computer keyboards, computer screens, computer touch-screens, cots, counters, countertops, CPAP masks, CPAP units, CPR training devices, CPR training manikins, crash carts, cribs, CT equipment, curing lights, curtains, cuspidors, nonporous cutting boards, dental impressions, dental trays, dental chair surfaces, dental equipment surfaces, dialysis treatment equipment surfaces, diaper changing tables, diaper pails, dictating machines, dissection work tables, diving suits, diving snorkels, diving equipment, diving masks, door handles, doorknobs, drinking fountain exteriors, drug preparation equipment, drug preparation hoods, dry suits, dumbbells, elevator buttons, elevator panels, emergency room stretchers, emergency medical technician units, emergency rescue squad vehicles, EMT units, embalming tables, empty whirlpool tanks, endoscope light source units, endoscope machine surfaces, endoscope machine tubing, endoscopes, endoscopes surfaces, environmental patient care fixtures, equipment counters, ER stretchers, ER equipment surfaces, escalator and moving walkway handrails, exam equipment exam lights, exam room lights, exam room surfaces, exam tables, examination equipment, examination lights, exam room lights, examination room surfaces, examination tables, eve wear, eve glasses, face shields, faucets, finger print counters, first call stretchers. fish nets, fish tank aerators, fish tank filters, fish tank gravel, fish tanks, fishing waders, fixtures, flea combs, floors, [sealed] [glazed] flower pots, food delivery carts, foot spa bowls, frequently touched surfaces, furniture, gaming machines, garbage cans, garbage compactors, garden equipment, garden storage bins, garden tools, gastroenterology equipment devices, gastroenterology equipment fixtures, glucometers, glucose meters, goggles, gonial lenses, grass mower blades, grooming facility surfaces, grooming tables, gym mats, hair care stations' fixtures, hair brushes, hair clippers, hair combs, hair driers, handcuffs, handrails, hand-pieces, harnesses, hazmat team equipment, hearse interiors, helicopters, high chairs, high-touch areas, home care equipment surfaces, horse trailers, hospice rooms, household fixtures, empty Hubbard tanks, empty hydrotherapy units, hygiene treatment surfaces, hyperbaric chamber surfaces, IC pumps, immobilization devices, implements, incubators, infant care equipment, infant care warmers, infant changing tables, infant incubators, infant seats, infant transport incubators, infant warmers, infant warming equipment, Isolettes®, instrument reprocessing equipment, instrument trays, interior tubing lumens, IV poles, IV stands, IV pump surfaces, infusion pump surfaces, kennels, kidney dialysis equipment surfaces, kick buckets, kitchen fixtures, kitty litter boxes, kitty litter scoops, lab benches, lab fixtures, laboratory benches, laboratory fixtures, labor and delivery room surfaces, laryngoscopes, leashes, light lens covers, light pull

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chains, light switches, lights, litter boxes, locker room benches, lockers, lockup facility fixtures, loupes, manicure implements, marine vessel interiors, masks, mats, mattress covers, mayo stands, medication carts, micro-derma abrasion equipment, microkeratome surfaces, microscopes, monitors, mouth quards, MRI equipment surfaces, nail implements, nail station fixtures, nail station tables, non-critical devices, noncritical operating room lights, operating room surfaces, operating room tables, OR lights, OR surfaces, OR tables, non-food/feed contact surfaces, nonfood/feed preparation surfaces, food/feed contact surfaces, food/feed preparation surfaces, non-porous hazmat suits, non-porous plastic-covered menus, hazmat suits, ([laminated] [plastic])-covered menus, nursing station fixtures, OB/Gyn surfaces, OB/Gynecology department surfaces, occupational therapy surfaces, operating room lights, optical wear (excluding contact lenses), organ scales, oxygen hoods, oxygen units, paramedic units, patient care fixtures, patient beds, patient bedrails, patient chairs, patient lifts, patient curtains, patient bed mattresses, patient restraints, patient transport carts, patient transport vehicles, pedicure chairs, pedicure chair tubs, pedicure implements, PEEP units, pet carrier surfaces, pet care surfaces, pharmacy counters, pharmacy surfaces, phototherapy lights, physician office surfaces, physical therapy equipment surfaces, plush toys, play toys, laundry, uniforms, turnout gear, pruning shears, plastic mattress covers, play-care equipment, play mats, Plexiglas® hoods, poker machine surfaces, pooper scoopers, prisoner benches, protective eye wear, pulse oximeters surfaces, pumps, rails, razors, reception area fixtures, recreational devices, refrigeration units, remains bags, remote controls, reptile habitats, rescue dive team equipment, rescue squad equipment, respirator ventilators, respirators, respiratory therapy equipment, restraints, resuscitators, salon fixtures, scales, scissors, school fixtures, school lockers, scoop stretchers, scuba equipment, seats, self-contained breathing apparatus (SCUBA) equipment, shampoo bowls, shears, shower doors, shower surfaces, showers, shower stalls, sinks, skin care equipment surfaces, [SilkPeel™] dermal infusion equipment, sleeping mats, slit lamps, slot machines, slot machine handles, slot machine surfaces, soap containers, soap dishes, SPD equipment, specimen refrigerator units, splinting devices, squad benches, stalls, stair-chairs, stethoscopes, stools, stretchers, stuffed toys, stuffed pillows, suction devices, suction machines, suction units, supply cabinets, surgical tables, tabletops, surgical instruments, surgical devices, surgical implements, tanning beds, telemetry equipment, telephones, toilet facilities, toilets, toilet seats, toilet surfaces, toilet training equipment, training room surfaces, tonometer equipment surfaces, tonometer tip surfaces, tools, touch screens, toys, tooth brushes, trash can lids, trash cans, treatment hoods, transport vehicle interiors, ([train] [airplane] [helicopter] [automobile] [bus] [taxi] [limo] [ambulance] [patient] [yachts] [cruise ship interior] [transport vehicle]) surfaces, tree saws, tubing, tumbling mats and equipment, turf equipment, turf equipment blades, TV remote controls, unplugged hair driers, upholstered fixtures, van fixtures, van interiors, vehicle interiors, vending machine surfaces, ventilators, veterinary operating room lights, veterinary operating room tables, veterinary equipment surfaces, video poker machines [exteriors], walkers, walls, washing bowls, water bowls, waterproof mattresses, weight machines, weight scales, weight training equipment, wet suits, wheelchairs, whirlpool tubs, window sills, work stations, wrestling mats, workout machines, xray units and other[frequently touched] [high-touched],[similar] ([surfaces][areas]).

{NOTE: All <u>underlined</u> Surfaces above are soft surfaces and cannot be used in connection with disinfection or food-contact sanitization claims. If a soft surface is chosen, the underline does not need to appear on the market label.}

{End of Marketing Copy}

## **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Pre-clean all surfaces to be treated with this product. Apply this undiluted product by ([sponge], [rag], [cloth], [microfiber], [mop], [spray] or [immersion]) to wet surfaces thoroughly.

#### {Kill Claims:}

#### [Soft, Non-Food Contact Surface Sanitization]

This product kills the following organisms in 10 seconds on pre-cleaned soft surfaces at room temperature when used as directed:

- Enterobacter aerogenes (ATCC 13048)
- Staphylococcus aureus {ATCC 6538}

## [Hard, Non-Porous Non-Food Contact Surface Sanitization]

This product kills the following organisms in 10 seconds on pre-cleaned hard, non-porous non-food contact surfaces at room temperature when used as directed:

- Enterobacter aerogenes (ATCC 13048)
- Staphylococcus aureus (ATCC 6538)

## [Hard, Non-Porous Food Contact Sanitization]

This product kills the following organisms in 1 minute on pre-cleaned hard, non-porous food contact surfaces at room temperature when used as directed:

- Escherichia coli [E.coli] {ATCC11229}
- Staphylococcus aureus {ATCC 6538}

## [Hospital and General Disinfection] {or} [Bactericidal]:

This product kills the following bacteria in 2 minutes on pre-cleaned hard, non-porous surfaces at room temperature when used as directed:

- Acinetobacter baumannii {ATCC 19606}
- Escherichia coli –with ([extended beta–lactamase resistance] [ESBL]) [(E. coli)] {ATCC BAA-196}
- Enterobacter aerogenes (ATCC 13048)
- Carbapenem-resistant Klebsiella pneumoniae [(CRKP)] {ATCC BAA-1705}
- Listeria monocytogenes (ATCC 19117)
- Methicillin-Resistant Staphylococcus aureus [(MRSA)] {ATCC 33591}
- Mycobacterium bovis BCG [(tuberculosis)] [(TB)] {Organon Teknika Corp}
- Pseudomonas aeruginosa (ATCC 15442)
- Serratia marcescens (ATCC 14756)
- Salmonella enterica (ATCC 10708)
- Staphylococcus aureus {ATCC 6538}
- Vancomycin-Resistant Enterococcus faecalis [(VRE)] (ATCC 51559)

## [Virucidal\*]

This product kills the following viruses\* in 2 minutes on pre-cleaned hard, non-porous surfaces at room temperature when used as directed:

- Avian Influenza A Reassortant Virus [(H3N2)] {ATCC VR-2072}
- Swine Influenza A Virus [(H1N1)] [Strain A/Swine/Iowa/15/30] [(formerly known as "swine flu")] {ATCC VR-333}
- Rotavirus (Strain WA)
- Hepatitis B Virus\* [(HBV)] [Strain LeGarth]
- Hepatitis C Virus\* [(HCV)]
- Herpes Simplex Virus [(HSV-2)] {ATCC VR-734}
- Human Immunodeficiency Virus\* [(HIV-1)] [(associated with AIDS)] {HTLV-111B}
- Influenza A Virus [Strain A2/Hong Kong] {ATCC VR-544}
- Rhinovirus [Type 14] [RV-14] {ATCC VR-284}

#### [Fungicidal]

This product kills the following fungi in 2 minutes on pre-cleaned hard, non-porous surfaces at room temperature when used as directed:

• Trichophyton interdigitale [(formerly known as Trichophyton mentagrophytes)] [(Ringworm)] [(Athletes Foot)] {ATCC 9533}

[For Veterinary / Pet Care Use:]

## [Disinfection {or} [Bactericidal]

This product kills the following bacteria in 3 minutes on pre-cleaned hard, non-porous surfaces at room temperature when used as directed:

- Bordetella bronchiseptica [(kennel cough)] {ATCC 10580}
- Chlamydia psittaci [(parrot fever)] {ATCC VR-125}
- Streptococcus equi [(Strangles)] [(equine distemper)] {ATCC 33398}

[For Veterinary / Pet Care Use:]

#### [Virucidal\*]

[In addition to the other microorganisms listed on this label] This product kills the following viruses\* in 3 minutes on pre-cleaned hard, non-porous surfaces at room temperature when used as directed:

- Bovine Viral Diarrhea Hepatitis C Virus\* [BVDV Hepatitis C Virus\* Surrogate]
- Duck Hepatitis B Virus\* [DHBV Hepatitis B Virus\* Surrogate] [Strain LeGarth]
- Canine Distemper Virus (ATCC VR-128)
- Canine Para-Influenza Virus (ATCC VR-666)
- Feline Leukemia Virus (American Bioresearch (CrFK cells))
- Infectious Bovine Rhinotracheitis Virus (ATCC VR-188)
- Murine Norovirus [Strain MNV-G]

{Contact time listed on the market label will be based on label claims and individual microorganism contact times.}

{The following paragraph must be included when farm premise uses are used:}

## [Additional Special Animal /Veterinary/Pet Care Cleaning ([Sanitizing] [Disinfection]) of Surface Instructions:]

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barn, pens, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with this product and rinse with water. Then saturate all surfaces with this product. Treated surfaces must remain wet for 3 minutes to kill all microorganisms listed on this label. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels, scrapers used in removing litter and manure. Ventilate buildings, cars, trucks, boats and other closed spaces. Do not house animals or employ equipment until treatment has set, dried or absorbed. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waters with soap or detergent.

#### {The following paragraph is required when the product is for small, non-farm animal care facility uses:}

Prior to surface cleaning and disinfection, remove visible debris such as animal excrement and bedding materials such as blankets, litter, wood chips, hay or straw.

## {The following paragraph is required when the Avian Influenza A kill claim appears on a spray bottle label:}

For disinfection of Avian Influenza A, use this product as a spray only for surfaces that are not conducive to treatment by immersion or excess liquid. Food and drink dispensing and preparation surfaces must be rinsed with potable water prior to use.

#### {The following paragraph is required when the label bears HIV-1, HBV, and/or HCV kill claims:}

\*HIV-1, HBV and HCV Precautions: This product kills HIV-1, HBV and HCV on pre-cleaned hard, non-porous surfaces/objects previously soiled with blood/body fluids in health care or other settings in which there is an expected likelihood of soiling of hard, non-porous surfaces/objects with blood/body fluids, and in which the surfaces/objects likely to be soiled can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 [(HIV-1)] [(associated with AIDS)], Hepatitis B Virus [(HBV)], and Hepatitis C Virus [(HCV)] Special instructions for cleaning against HIV-1, HBV and HCV on surfaces/objects soiled with blood/body fluids:

**Personal Protection:** Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks and eye coverings.

**Cleaning Procedure:** Blood and body fluids must be thoroughly cleaned from surfaces/objects before disinfection. **Contact Time:** Allow hard, non-porous surfaces to remain wet for 2 minutes to kill HIV-1, HBV and HCV.

**Infectious Materials Disposal:** Cleaning materials used that may contain blood/body fluids must be autoclaved and/or disposed of in accordance with local regulations for infectious materials disposal.

#### {The following paragraph is required with the product bears human medical use sites/articles/surfaces:}

This product is not to be used as a terminal sterilant or high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter sterile areas of the body. This product may be used to pre-clean critical and semi-critical medical devices prior to sterilization or high-level disinfection.

## [Cleaning and Deodorizing Directions]

{Note: Cleaning and Deodorizing Directions are optional except if cleaning/deodorizing marketing claims are listed on the label}

**For surface cleaning:** To clean surfaces, saturate surfaces with this product by spray, mop, rag, towel, paper towel, pour, or immersion then wipe surface clean. Repeat, if necessary, until surfaces are visibly clean. Discard paper towels or launder cloth towels before reusing.

For cleaning walls and floors: In a clean bucket, dilute 2 to 4 oz. of this product per gallon of warm, clean, potable water. Thoroughly damp-mop using a clean ([microfiber] [mop], [cloth towel] or [sponge]). Allow to air dry.

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For use as a [pre-cleaning] [pre-laundering] spot or stain removal spray treatment: Thoroughly spray soiled area, allow to remain wet for at least 10 seconds before laundering as usual.

For use as a [surface] deodorizer: Apply to surface and either wipe off or allow to air dry.

**For use as a pre-cleaning ([instrument] [device]) soak:** Fill appropriately-sized container with a sufficient amount of this product to allow for complete submersion of items. Place items into solution and allow to soak for 2 minutes. Be certain to flush lumens of hollow devices with this product. Remove items and rinse. For critical and semi-critical items, follow with the appropriate cleaning and disinfection or sterilization process. Change solution as needed, i.e., when the solution becomes dirty or visibly soiled.

For use as a ([pre-cleaning [pre-treatment]) ([Instrument] [device]) spray: Place item into a suitable container. Thoroughly spray item with this product until drenched, thoroughly rinse. Follow with an appropriate terminal cleaning and sterilization/disinfection process.

For use as a pre-cleaning wipe: Saturate a clean sponge, gauze wipe or cloth with this product. Thoroughly wipe ([item] [device] [instrument] [exterior scope surface]) until visibly clean. Dispose of or launder spent materials before reuse.

{Note to reviewer: Should endoscopes be chosen as a surface, the following Directions for Use paragraph is required}

For use to ([pre-clean] [pre-treat]) flexible endoscopes prior to handling during terminal reprocessing: Immediately after use and while the scope is still connected to the light source, thoroughly wipe the exterior surface of the insertion tube using a sponge saturated with this product until visibly clean. Flush the internal channels of the scope, suctioning this product through the internal channels, through the suction tubing and into the suction jar until the solution is visibly clean. Cover the scope and transport to the appropriate area for terminal reprocessing. This product is not be used as a sanitizer or disinfectant for endoscopes.

For use as an ultrasonic cleaning solution: Prepare the ultrasonic bath using a dilution ratio of 1 fl. oz. of this product with 1 quart of clean, potable water. Place items into the ultrasonic bath, activate unit and allow unit to operate until items are visibly clean. Remove items and thoroughly rinse under running cool tap water. Proceed with appropriate disinfection or sterilization process.

For use as a cleaner for hair clippers and electric shears: Disconnect from the electrical supply. Hold in the downward position and apply this product directly onto the blades, making sure the solution does not drain into the housing. Wipe dry with a clean, soft cloth.

## [Disinfection Directions]

For use as a hard, non-porous non-food contact surface disinfectant/virucide/fungicide: Apply this product to pre-cleaned surfaces by sponge, cloth, microfiber, mop, spray, pour or immersion to wet surfaces thoroughly. Allow to remain wet for ([2] [3]) {as appropriate} minutes [at room temperature], then wipe dry using a [microfiber] mop, clean paper or cloth towel, or rinse surface using potable water and wipe surface dry or allow to air dry. Discard or launder spent materials before reuse.

For cleaning and disinfecting dental impressions: Apply this product until thoroughly drenched, then rinse with potable water and wipe or air dry. Reapply product to thoroughly wet the surfaces and allow to remain wet for ([2] [3]) {as appropriate} minutes. Rinse with potable water and wipe or air dry.

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For use as a non-critical medical item disinfection immersion solution: Thoroughly pre-clean items being sure to remove all gross filth and heavy soil, then rinse and dry. Allowing for complete submersion of item(s), place pre-cleaned item(s) into an appropriate container that has been filled with this product. Flush lumens of hollow devices with this product. Allow item(s) to remain submerged for ([2] [3]) (as appropriate) minutes. Remove, rinse with clean, potable water and dry. Change solution daily or when it becomes visibly soiled or discolored.

For use as a disinfectant for hair clipper and electric shear(s): Disconnect from the electrical supply. Hold in a downward position and apply this product to thoroughly wet the blades, making sure the solution does not drain into the housing. Wipe soil from blades. Reapply and allow to remain wet for ([2] [3]) (as appropriate) minutes, then wipe dry with a clean cloth. Lubricate blades per the manufacturer's instructions.

For use as an ([eye glass] [protective eye wear] [loupe]) cleaner [and disinfectant]: Thoroughly wet entire surface and wipe clean using a soft cloth. Reapply and allow surface to remain wet for ([2] [3]) {as appropriate} minutes. Re-wipe the surface using a fresh cloth. This product should not be used on contact lenses.

## [Sanitization Directions]

## [Soft, Non-Food Contact Surfaces]

**For soft, non-food contact surface sanitization:** Apply this product to pre-cleaned soft surfaces by sponge, cloth, microfiber, mop, spray, pour or immersion to wet surfaces thoroughly. Allow soft surfaces to remain visibly wet for 10 seconds at room temperature then wipe surfaces using a clean [microfiber] mop, paper or cloth towel, or rinse surface using potable water or allow to air dry. Discard or launder spent materials before reuse.

## [Hard, Non-Porous Non-Food Contact Surfaces]

For hard, non-porous, non-food contact surface sanitization: Apply this product to pre-cleaned hard, non-porous surfaces by sponge, cloth, microfiber, mop, spray, pour or immersion to wet surfaces thoroughly. Allow hard, non-porous surfaces to remain visibly wet for 10 seconds at room temperature then wipe surfaces using a clean [microfiber] mop, paper or cloth towel, or rinse surface using potable water or allow to air dry. Discard or launder spent materials before reuse.

For use as a sanitizer for hair clipper and electric shear(s) (Not For Use in California): Disconnect from the electrical supply. Hold in a downward position and apply this product to thoroughly wet the blades, making sure the solution does not drain into the housing. Wipe soil from blades. Reapply and allow to remain wet for 10 seconds, then wipe dry with a clean cloth. Lubricate blades per the manufacturer's instructions.

For use as a personal care implement immersion sanitizer (*Not For Use in California*): Immerse pre-cleaned implements (such as combs, brushes, razors, manicure/pedicure tools, tweezers and scissors) in this product. Allow items to remain immersed for at least 10 seconds. When ready for use, thoroughly rinse and/or wipe dry using a clean cloth or paper towel. Change solution at least daily or when solution becomes visibly dirty or discolored.

For use as an ([eye glass] [protective eye wear] [loupe]) cleaner [and sanitizer]: Thoroughly wet entire surface and wipe clean using a soft cloth. Reapply and allow surface to remain wet for 10 seconds. Re-wipe the surface using a fresh cloth. This product should not be used on contact lenses.

## [Hard, Non-Porous Food Contact Surfaces]

**For hard, non-porous food contact surface sanitization:** Apply this product to pre-cleaned surfaces by sponge, cloth, microfiber, mop, spray, pour or immersion to wet surfaces thoroughly. Allow hard, non-porous food contact surfaces to remain visibly wet for 1 minute at room temperature then wipe surfaces using a clean [microfiber] mop, paper or cloth towel, or rinse surface using potable water or wipe surface dry or allow to air dry. Discard or launder spent materials before reuse.

{Note: Choose the appropriate Storage and Disposal directions from below}

{For non-refillable household/residential use products:}

## Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

**Pesticide Storage:** Store in original container in a cool, well ventilated, locked storage area. **Pesticide Disposal and Container Handling:** Non-refillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available.

{For non-refillable containers:}

## Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

**Pesticide Storage:** Store in original container in a cool, well-ventilated [(preferably locked)] area inaccessible to children and pets. **Pesticide Disposal:** To avoid waste, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program. **Container Handling:** Non-refillable container. Do not reuse or refill this container. Discard container and put in trash or offer for recycling if available.

{For refillable spray bottles and other containers:}

## Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

**Pesticide Storage:** Store in original container in a cool, well-ventilated, [preferably locked] area inaccessible to children and pets. **Pesticide Disposal:** To avoid waste, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program. **Container Handling:** Refillable container. Refill this container with this product only. Do not reuse this container for any other purpose. Cleaning before refilling is the responsibility of the refiller. Cleaning the container before final disposal is the responsibility of the person disposing of the container. To clean the empty container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full of water. Agitate vigorously and dispose of contents on site or at an approved waste disposal facility. Offer container for recycling, if available, or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved state and local authorities.

## PRECAUTIONARY STATEMENTS

#### **Hazards to Humans and Domestic Animals**

**CAUTION:** Harmful if inhaled or absorbed through skin. Causes moderate eye irritation. Avoid breathing vapors and contact with eyes, skin or clothing. Wear appropriate personal protective equipment based on safe work practices. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

#### First Aid

If Inhaled	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> </ul>	
If on Skin	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul>	
If in Eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>	

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact ([{insert appropriate emergency contact number}] for emergency medical treatment information [the National Pesticides Information Center (NPIC) at 1-800-858-7378 for non-emergency information concerning this product]).

{The First Aid statements may appear in grid or paragraph format.}

## **Physical or Chemical Hazards**

Do not use or store near heat or open flame.

[For product or technical information contact {insert appropriate contact information}].

# Manufactured in the U.S.A. for: Micro-Scientific, LLC.

[Corporate Offices:] 755 Tri State Parkway Gurnee, IL 60031 U.S.A. Telephone: 1-888-253-2536

[Product] [Code] [Re-order] [Product Code] [Order] [No]: \_\_\_\_\_

[Opti-Cide® is a registered trademark of Micro-Scientific, LLC.]

## **Emerging Viral Pathogens Claim**

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses
- Small Non-Enveloped Viruses

For an emerging viral pathogen that is a/an	following the directions for use for the following supporting organism(s) on the label:
Enveloped virus	Rhinovirus [Type 14] [RV-14] {ATCC VR-284}
Enveloped virus	Rotavirus (Strain WA)
Large, non-enveloped virus	Rhinovirus [Type 14] [RV-14] {ATCC VR-284}
Small, non-enveloped virus	Murine Norovirus [Strain MNV-G]

[Product Name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [Product Name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product Name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.